

DRAFT -- intended only to illustrate a discussion of format



U.S. Department of Health & Human Services



U.S. Food and Drug Administration

GARDASIL: Safety Alert

Sit or lie down for 15 minutes after a GARDASIL injection to prevent fainting (syncope) and falling.

Product:	Gardasil
Use:	Vaccine for cancer of the cervix, vulva, and vagina and genital warts in women
Issue:	Injury from fainting and falling down after a shot
Action:	<ul style="list-style-type: none">Sit or lie down for 15 minutes after a shot to prevent fainting and fallingTell your doctor or nurse if you start sweating, feel faint or dizzy, have ringing in your ears or vision changes.

Key Facts

- Fainting with jerking movement (tonic-clonic movements) and seizure-like activity have been reported after injections of Gardasil and other vaccines for teenagers.
- These side effects occur at about the same rate after shots of Gardasil or other vaccines for teenagers.
- Gardasil only works if it is used before a woman is exposed to HPV.
- Women who get Gardasil should still have their regular pap tests to screen for cervical cancer.

Background

Since doctors starting using Gardasil, the FDA (Food and Drug Administration) and CDC (Center for Disease Control and Prevention) have kept a watch on the safety of Gardasil.

From information in safety reports, FDA and CDC believe that Gardasil is a safe and effective vaccine. Its benefits are greater than its risks.

For more information



Ask your doctor for the Vaccine Information Statements (VISs). This information sheet explains the benefits and risks of a vaccine to teenagers who get a vaccine, their parents, or their legal guardians. Federal Law requires that VISs be given out with certain vaccine shots.

CONTACT INFO???

LINKS To Gardasil information labeling, etc

To get e-mail updates on Gardasil, click on the icon. (or [Click here](#))



Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).



Page Last Updated: 02/19/2010

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MERIDIA: Early Safety Alert

Meridia may cause serious heart problems such as heart attack, stroke, cardiac arrest, or death

Product:	Meridia (sibutramine hydrochloride)
Use:	Helps people lose weight and keep it off when used with calorie control
Issue:	Higher number of serious heart problems (heart attack, stroke, cardiac arrest, or death)
Action:	None

Key Facts

- Patients taking Meridia in a study had a higher number of heart problems, including heart attack, stroke, cardiac arrest, or death
- Do not take Meridia if you have heart disease, congestive heart failure (CHF), abnormal heart rhythm, or stroke

For more information



Talk with your doctor about whether Meridia is right for you.

Ask your doctor or pharmacist for the information written for healthcare professionals or for the Medication Guide written for patients.

[LINKS To Related Information]

- Information for [Meridia \(sibutramine hydrochloride\)](#)¹
 - [Follow-Up to the November 2009 Early Communication about an Ongoing Safety Review of Sibutramine, Marketed as Meridia](#)²
- 1/21/2010

Contact us

Report side effects from the use of Meridia (sibutramine) to FDA's MedWatch Adverse Event Reporting program



- 1-800-332-1088
- 1-800-FDA-0178 Fax

MedWatch Online

Regular Mail: Use postage-paid [FDA Form 3500](#)

Mail to: MedWatch

5600 Fishers Lane
Rockville, MD 20852-9787

The FDA is committed to keeping you informed about its ongoing safety reviews of drugs. FDA will communicate its findings to the public as soon as this review is complete.

To get e-mail updates on Meridia, click on the icon. (or Click here)



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